

Via ECF

March 17, 2023

Hon. Katherine Polk Failla
Thurgood Marshall
United States Courthouse
40 Foley Square
New York, NY 10007

*Re: In re: Chantix (Varenicline) Marketing, Sales Practices and Products
Liability Litigation (No. II), 22-MD-3050 (KPF), 22-mc-3050 (KPF) (S.D.N.Y.)*

Dear Judge Failla:

We are Temporary Plaintiffs' Counsel in the above-captioned action (the "Action"), and we write in response to Your Honor's Order No. 1. In accordance with Order No. 1, we provide the Court with our views regarding (i) how lead counsel and liaison counsel should be structured – including whether a single set of lead counsel and liaison counsel should be appointed for all plaintiffs; and (ii) the best process for appointment of leadership.

Counsel for all Plaintiffs have conferred, and are pleased to report we have reached a consensus regarding the proposed leadership structure that we believe will achieve efficiency and economy in the prosecution of the Action, without jeopardizing fairness to the parties. Temporary Plaintiffs' Counsel will file a separate letter under seal containing our recommendations as to appointees. Temporary Plaintiffs' Counsel proposes that a single group of counsel, composed of firms which have filed actions by consumer and third-party payor ("TPP") clients, represent the proposed Classes. The proposed structure includes a three-firm co-lead counsel ("Interim Co-Lead Counsel") and single firm liaison counsel ("Liaison Counsel"). To ensure fairness to both Classes, Temporary Plaintiffs' Counsel further recommends that the Court appoint a Plaintiffs' executive committee, comprised of two firms representing the consumer class and another firm representing the TPP class ("Plaintiffs' Executive Committee"). As set forth herein, Temporary Plaintiffs' Counsel believe the proposed leadership structure is necessary and warranted for this Action given the complex claims asserted and broad scope of consumer and TPP clients representing the proposed Classes. The proposed structure will also provide the most resources to go head-to-head with one of the world's largest pharmaceutical corporations.

As discussed further below, because Plaintiffs have reached consensus, no further proceedings are needed to appoint leadership. Therefore, Temporary Plaintiffs' Counsel respectfully requests that the Court enter the Proposed Order filed concurrently herewith and appoint the firms identified by separate letter.

I. Factual Background

Plaintiffs in the various actions are persons and TPPs that have purchased varenicline-containing medications under the brand name Chantix® (“Chantix”) manufactured and sold by Defendant Pfizer, Inc. (“Pfizer”). Plaintiffs allege that during the Class Period, Chantix was contaminated with dangerously high levels of N-nitroso-varenicline, a carcinogenic substance. Pfizer’s drugs also were not manufactured in compliance with current Good Manufacturing Practices (cGMPs). Because nitrosamines are not active or inactive components of Chantix, the presence of nitrosamine contaminants in a drug such as Chantix, as well as Pfizer’s significant cGMP violations, each rendered its product adulterated and misbranded under federal and analogous state laws, and therefore economically worthless and illegal to sell.

Certain Plaintiffs bring claims on behalf of TPPs that purchased Chantix, while other Plaintiffs bring claims on behalf of consumers of Chantix. Plaintiffs bring various claims on behalf of each of the Classes, including claims for breach of express and implied warranty, fraud, negligent misrepresentation and omission, violation of state consumer protection laws, violation of the Magnuson-Moss Warranty Act, negligence, negligence per se, and unjust enrichment.

On December 22, 2022, the Judicial Panel on Multidistrict Litigation issued a Transfer Order under 28 U.S.C. §1407 centralizing the various Chantix cases to the Southern District of New York, finding it would best promote the just and efficient conduct of this litigation. ECF No. 1.

II. A Three-Firm Interim Co-Lead Counsel with Liaison Counsel and Three-Firm Plaintiffs’ Executive Committee is the Appropriate Structure Given the Complexity of the Claims

Temporary Plaintiffs’ Counsel believes that the proposed structure is the best way to successfully litigate the Action and receive the best recovery for Plaintiffs and the Classes. Given the complexity of the claims, the number of claims alleged, and the sophistication of the clients involved, the three-tiered structure will maximize recovery, while ensuring efficient prosecution of the claims. Because both consumers and TPPs are bringing claims against Pfizer, having a leadership structure as proposed will best ensure that both Classes are fairly represented at each stage of the proceedings.

Courts routinely have appointed a multi-tiered structure in similar, complex MDLs involving drug products. *See, e.g.,* Case Management Order No. 6 Approving Plaintiffs’ and Defendants’ Leadership Structure, *In re: Valsartan Products Liability Litig.*, No. 1:19-md-02875-RBK-JS, ECF No. 96 (D.N.J. May 6, 2019) (appointing co-lead counsel, liaison counsel, executive committee, and three separate plaintiffs’ steering committees in large, complex multi-district litigation concerning sale in the U.S. of prescription generic drugs containing Valsartan, which were alleged to contain cancer-causing contaminants); Order Appointing Counsel, *In re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, ECF No. 40 (D. Kan. Sept. 12, 2017) (appointing co-lead counsel, liaison counsel, and plaintiffs’ steering committee in large, complex multi-district litigation concerning anticompetitive conduct in the epinephrine autoinjector market); Supplemental Pretrial Order #8, *In re Philips*

Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Prods. Liability Litig., No. 2:21-mc-1230-JFC, ECF No. 395 (W.D. Pa. Feb. 15, 2022) (appointing four co-lead counsel, liaison counsel, and executive committee in litigation concerning recall of Philips' CPAP devices); *Diaz v. Univ. of S. Cal.*, No. 20-cv-4066, 2020 WL 5044419, at *4 (C.D. Cal. July 17, 2020) (appointing tripartite co-lead interim leadership structure). Thus, a multi-tiered structure has been established as the best way to represent various interests in complex actions with various claims alleged.

Because Pfizer is a large corporation with substantial resources and top-tier representation, the proposed structure also ensures that Plaintiffs will have the necessary resources to litigate the Action. By appointing a three firm Interim Co-Lead Counsel and three firm Plaintiffs' Executive Committee, Plaintiffs will have the essential lawyers and capital needed to oppose Pfizer.

Each firm selected to serve in the proposed structure will play a specific, yet vital role in the prosecution of the Action. During all phases of the litigation, Interim Co-Lead Counsel will: (i) organize and supervise the efforts of plaintiffs' counsel in a manner to ensure that plaintiffs' pretrial preparation is conducted effectively, efficiently, expeditiously, and economically; (ii) delegate work responsibilities and monitor the activities of plaintiffs' counsel to assure that schedules are met and unnecessary expenditures of time and expense are avoided; (iii) speak for plaintiffs at all court conferences and hearings; (iv) initiate and conduct discussions and negotiations with counsel for Pfizer on all matters, including settlement; (v) determine (after consultation with other co-counsel as may be appropriate) and present in briefs or oral argument to the Court and opposing parties the position of the Plaintiffs on all matters arising during the proceedings; (vi) enter into stipulations with opposing counsel as necessary for the conduct of the litigation; (vii) select, consult with, and employ experts, as necessary, for Plaintiffs; (viii) initiate and conduct discovery on Plaintiffs' behalf, and coordinate its efficiency; (ix) serve as the primary contact for all communications between Plaintiffs and Pfizer; (x) coordinate the work of preparing and presenting all of Plaintiffs' claims and otherwise coordinate all proceedings; (xi) encourage and enforce efficiency among all Plaintiffs' counsel; (xii) assess Plaintiffs' counsel for the costs of the Action; (xiii) consult with Plaintiffs' Executive Committee to fulfill their obligations as Interim Co-Lead Counsel shall direct; and (xiv) perform such other duties in connection with prosecuting the claims in this Action.

Liaison Counsel will be responsible for performing the duties and responsibilities described in the MCL 4th §10.221, including facilitating and expediting communications with and among Plaintiffs' counsel and fulfilling such other duties as requested by the court or Interim Co-Lead Counsel. Liaison Counsel will also assume responsibility for the following: (i) receiving orders, notices, correspondence, and telephone calls from the court and the clerk of the court on Plaintiffs' behalf; (ii) preparing and transmitting copies of such orders and notices on Plaintiffs' behalf; (iii) receiving orders and notices from the Judicial Panel on Multidistrict Litigation; (iv) maintaining complete files with copies of all documents served and make such files available to Pfizer's counsel on request; (v) maintaining and making available to all counsel and the Court an up-to-date service list; and (vi) accepting service for all plaintiffs in all cases of notices, orders, pleadings, motions, discovery, and memoranda. Liaison Counsel will also handle administrative matters, as

well as any substantive matters which Interim Co-Lead Counsel may assign. Finally, Plaintiffs' Executive Committee will represent the uniquely situated sets of Plaintiffs – the consumers and TPPs. As discussed below, a separate set of counsel is necessary to represent the differing positions of these sets of Plaintiffs.

To ensure that the work performed by Interim Co-Lead Counsel, Liaison Counsel, and the Executive Committee is performed effectively and efficiently without unnecessary duplication, we propose a time and expense protocol be implemented for work performed by counsel for Plaintiffs in the Action. Reports of time and expenses can be submitted *in camera* to the Court for review on a semi-annual or quarterly basis. This will allow Interim Co-Lead Counsel to ensure each month that the firms are only completing authorized and approved work, as well as reject any unauthorized time. Periodic *in camera* time and expense submissions, while more work for Plaintiffs' counsel, also ensures accountability and reduces the likelihood of disputes about costs or fees at the conclusion of this matter. Additionally, the Court can confirm that the time and expenses incurred are reasonable and for the benefit of the Classes.

III. Because The Various Plaintiffs Firms Agree to the Proposed Structure, The Court May Enter the Proposed Order

Here, the various Plaintiffs have consented to this “private ordering.” *Manual for Complex Litig.* §21.272 (private ordering is when “lawyers agree who should be lead class counsel and the court approves the selection after a review to ensure that the counsel selected is adequate to represent the class interests”). Such private ordering is the most common and desirable means of selecting class counsel. *See id.* at §10.22 (efforts by attorneys to “coordinate their activities without the court’s assistance . . . should be encouraged”); *In re Cmty. Bank of N. Va. Mortg. Lending Practices Litig.*, MDL No. 1674, 2011 WL 4382942, at *2 (W.D. Pa. Sept. 20, 2011) (“[T]he private ordering method of selecting interim lead counsel has long been the preferred approach.”). Thus, the Court may enter the Proposed Order without further submissions from counsel.

IV. A Plaintiffs Executive Committee Is Appropriate Given the Magnitude of the Litigation

When appointing counsel, the MCL 4th directs courts to consider “whether designated counsel fairly represent the various interests [presented] in the litigation—where diverse interests exist among the parties, the court may designate a committee of counsel representing different interests.” MCL 4th §10.224. The court or lead counsel may task committees with preparing briefs or conducting portions of the discovery program if one lawyer cannot do so adequately. *Id.* Where, as here, group members’ interests and positions are dissimilar, courts find they should have representation in decision making. Given the magnitude of this litigation, a Plaintiffs’ Executive Committee would be useful in managing and coordinating the prosecution of this litigation, as it has been in other successfully prosecuted consumer class actions.

Courts have regularly appointed multi-firm co-lead and executive committees in complicated and resource-intensive consumer cases, such as the one here. *See, infra, In re: Valsartan Products Liability Litig.*, ECF No. 96; *In re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litig.*, ECF No. 40; *In re Philips Recalled CPAP, Bi-Level CPAP, and Mechanical Ventilator Prods. Liability Litig.*, ECF No. 395. This is especially true where plaintiffs are uniquely situated and have differing positions from other sets of plaintiffs.

Movants are aware the Court indicated that it was not initially inclined to appoint a plaintiffs' executive committee. *See* CMO No. 1 (ECF 6), at Part VI.E. However, Movants submit appointing a committee at the outset has a number of practical efficiencies. That this MDL currently involves only a single defendant is not dispositive.¹ Pfizer is one of the largest, if not the largest, pharmaceutical firms in the world. It has retained DLA Piper, which is one of the largest law firms globally by head count and revenue. DLA Piper has already entered appearances for no fewer than 12 of its attorneys. There is little question Movants will need to pool their staff and financial resources to scale efficiently to meet the stout defense Pfizer and its counsel will present.

For the foregoing reasons, Temporary Plaintiffs' Counsel request that the Court appoint a single group of counsel to represent the proposed Classes, comprised of a three-firm Interim Co-Lead Counsel, single firm Liaison Counsel, and three-firm Plaintiffs' Executive Committee.

Respectfully,



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cc: All Counsel of Record (via ECF)

¹ *See, e.g., In re Shop-Vac Marketing & Sales Pracs. Litig.*, MDNL No. 2380, 2013 WL 183855 (M.D. Pa. Jan. 13, 2013) (appointing interim co-lead counsel and executive committee in MDL involving only one manufacturer defendant and one retailer defendant).